

time the above identified Office action was mailed. Claim 1 has been amended. Support for the amended claim comes from at least pages 14, lines 9-16 and 16, lines 8-23.

The following remarks are numbered to correspond to the numbering used in the referenced Office action (Paper Number 10).

#### 4. Priority Claim

Applicants have amended the specification to comply with the conditions for receiving the benefit of the filing date under 35 U.S.C. 119(e) of provisional application 60/050,633 filed June 24, 1997.

#### 5-6. The Provisional Obviousness Double Patenting Rejection

The Office has provisionally rejected claims 1-9 and 25-29 under the judicially created doctrine of obviousness type double patenting as being unpatentable of claims 1-7, 10-16, 20, 35-39 and 41-44 of copending application serial no. 09/183824.

No action is believed required by Applicant as the alleged conflicting claims have not in fact been patented.

#### 7-8. The Rejection of the Claims under 35 U.S.C. 102(b)

The Office has rejected claims 1-5 and 25 under 35 U.S.C. 102(b) as being anticipated by Kumpel et al., (1994) Hum. Antib. Hybridomas 5(3 and 4):143-151 (Kumpel et al.). The Office contends that Kumpel et al. teach human monoclonal antibodies wherein substantially all of the oligosaccharide is a G2 oligosaccharide referring to Table 1 and columns 1-3 at page 149 of Kumpel et al. (Paper Number 10, page 3) The Office further contends that the tissue culture media of Kumpel et al. is a

pharmaceutically acceptable carrier (Paper Number 10. page 3).  
Applicants respectfully traverse.

Kumpel et al. describe a monoclonal antibody, 2B6, produced from an EBV-transformed B-lymphoblastoid cell line and alleged to contain 78.7% digalactosyl oligosaccharides, 17.7% monogalactosyl oligosaccharides and 3.6% agalactosyl oligosaccharides after chemical removal of terminal sialic acid residues. (Table 1 and accompanying text, page 145, Kumpel et al.). Table 1 of Kumpel et al. also show that 21.7 % of the oligosaccharides in the original preparation are sialylated (Table 1 and text at page 146). According to Kumpel et al. a substantial portion (21.7%) of the galactosylated oligosaccharides (some combination of either mono- or digalactosylated) terminate in a sialic acid residue and not galactose residue. Therefore the 2B6 antibody preparation described is not a glycoprotein wherein substantially all of the oligosaccharide is a G2 oligosaccharide. In fact, it appears that the 2B6 preparation is a heterogenous mixture of several different glycoforms which typify the preparations of the prior art.

In view of the foregoing, a discussion of whether or not a tissue culture media would anticipate a pharmaceutically acceptable carrier would appear moot.

Applicants respectfully request reconsideration and withdrawal of the pending rejection of the claims under 35 USC 102(b).

10. The Rejection of the Claims under 35 U.S.C. 103(a)

The Office has rejected claims 1-9 and 25-29 under 35 U.S.C. 103(a) as being unpatentable over Kumpel et al., in view of US

patent 5,834,251 by Maras et al. (Maras et al.). The Office contends that Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison the same antibody which is produced in a manner that results in low levels of G2 (Paper Number 10). The Office further contends that Maras et al. teach that a galactosyltransferase enzyme can be used to modify the oligosaccharide profile on a glycoprotein while relying on the specification for disclosure of clinical uses of various antibodies. Applicants respectfully traverse.

As discussed in the previous section Kumpel et al. do not describe or suggest a composition comprising a glycoprotein wherein substantially all of the oligosaccharide is a G2 oligosaccharide. Importantly, Kumpel do not describe increased lysis of target cells for an antibody after chemical removal of the sialic acid residues. The activity data described by Kumpel is for a heterogenous glycoprotein preparation and not a composition wherein substantially all of the oligosaccharide is a G2 oligosaccharide. In fact, as described above almost 22 % of the galactosylated oligosaccharides detected by Kumpel et al. terminated in a sialic acid residue. Therefore Kumpel et al., alone or in combination with Maras et al. fail to provide the motivation to produce Applicant's claimed compositions but rather suggest that some heterogenous glycoprotein preparation can be prepared.


In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the pending rejection of the claims under 35 U.S.C. 103.

CONCLUSION

Applicants respectfully request that the foregoing amendments be considered and entered in the file history of the above-identified application. It is submitted that the claims are now in condition for allowance. It is therefore earnestly solicited that such a final favorable disposition is made. The Examiner is invited to telephone Jeffrey S. Kubinec, (Reg. No. 36,575) at (650) 225-8228 if deemed helpful to clarify and advance prosecution.

Respectfully submitted,  
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